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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.      |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/591,096  | 05/11/2007  | David W. Boykin      | 1523/2 PCT/US       | 6354                  |
| 25297   | 7590        | 07/01/2010           | EXAMINER            |                       |
| JENKINS, WILSON, TAYLOR & HUNT, P. A.<br>Suite 1200 UNIVERSITY TOWER<br>3100 TOWER BLVD.,<br>DURHAM, NC 27707 |             |                      |                     | STOCKTON, LAURA LYNNE |
| ART UNIT  |             | PAPER NUMBER         |                     |                       |
| 1626  |             |                      |                     |                       |
| MAIL DATE   |             | DELIVERY MODE        |                     |                       |
| 07/01/2010  |             | PAPER                |                     |                       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 10/591,096               | BOYKIN ET AL.       |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Laura L. Stockton, Ph.D. | 1626                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on April 12, 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-43 is/are pending in the application.  
 4a) Of the above claim(s) 2-15 and 30-43 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 16-21, 23 and 25 is/are rejected.  
 7) Claim(s) 1,22, 24 and 26-29 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :October 4, 2006 and October 10, 2006.

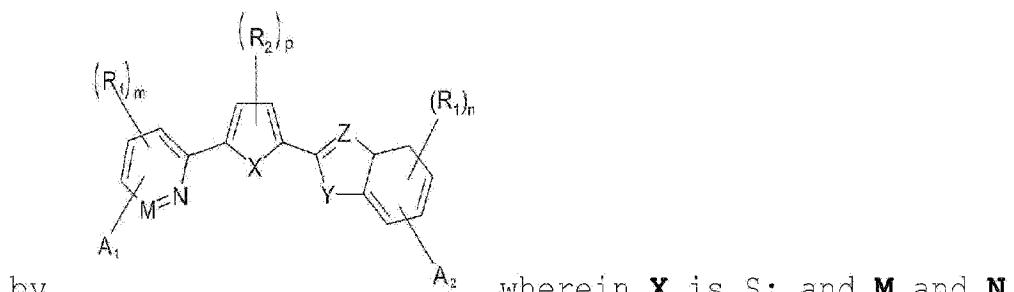
**DETAILED ACTION**

Claims 1-43 are pending in the application.

### *Election/Restrictions*

Applicant's election of Group IV (reproduced below) in the reply filed on April 12, 2010 is acknowledged.

**Group IV.** Claims 1 and 16-29 (in-part), drawn to methods of using compounds of Formula (I) represented

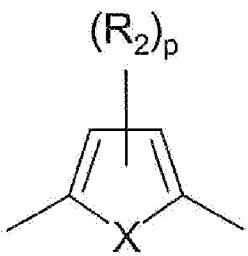


are each CH; Z is N and Y is NR<sub>3</sub>.

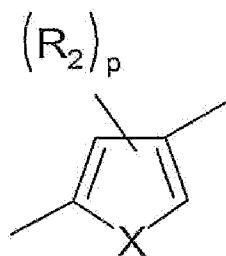
Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

**Note:** Subject matter wherein **L** represents either



, as shown above, or



and **X** is

S, in both instances, in formula (I) has been examined in elected Group IV.

Subject matter not embraced by elected Group IV and Claims 2-15 and 30-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 12, 2010.

It is suggested that in order to advance prosecution, the non-elected subject matter be cancelled when responding to this Office Action.

***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statement(s) filed on October 4, 2006 and October 10, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate

paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Specification***

Applicant is reminded to update the status of application(s) listed in the "Cross-Reference" on page 1 of the instant specification {i.e., the 371 application}.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21, 23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention.

In claim 16, lines 1-2 of claim, the phrase "the compound of Formula (I) comprises a compound of Formula (IV)" should be changed to "the compound of Formula (I) is a compound of Formula (IV)" because the use of "comprises" in Markush claim language is improper.

In claim 20, line 1 of claim, "each comprise" should be changed to "are each".

Claim 23 lacks antecedent basis from claim 1.

In claim 25, the phrase "pharmaceutically acceptable salt comprises" should be changed to "pharmaceutically acceptable salt is".

The US patent cited on Form 892, U.S. Patent 3,264,315, is done so to show the state of the prior art.

***Allowable Subject Matter***

Claims 1, 22, 24 and 26-29 are objected to for containing subject matter outside of the scope of elected Group IV. Independent Claim 1 presented directed solely towards the elected invention of Group IV would appear allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

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automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/  
Laura L. Stockton, Ph.D.  
Primary Examiner, Art Unit 1626  
Work Group 1620  
Technology Center 1600

July 1, 2010